

REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the above amendments and following remarks, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-33 are pending in this application. Claims 1-12 and 31-33 have been withdrawn from consideration by a previous amendment. Claims 13-30 are rejected in the Office Action mailed on March 3, 2008.

Initially, Applicants' attorneys would like to thank the Examiner for acknowledging Applicants' amendment filed October 25, 2007 and the Request for Continued Examination filed November 28, 2007.

II. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

On page 3 of the Office Action, the Examiner rejects claims 13, 15-25, and 27-30 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2,262,711 to Ludwin ("Ludwin") in view of U.S. Patent No. 4,193,401 to Marinello ("Marinello"). The rejections are traversed for at least the following reasons.

As presently understood by Applicants' attorneys, Ludwin is directed to a nebulizer. Because a nebulizer delivers a volatilized substance, in this case a medicament for treating respiratory ailments (*Ludwin*, page 1 left column, lines 1-5), it would be apparent to one of ordinary skill in the art that vaporization of the treating substance is necessary. In numbered paragraph 4 of the Office Action, the Examiner recognizes that pressure is used in Ludwin "to vaporize the medicine to the small pores of the sinus track." (Emphasis added.) Ludwin recites

in the left column on page 2, lines 5-18, that “air will be supplied from the compressor...through the tube...to the heating element...and this air causes a pressure upon the liquid medicament,” forcing the medicament through a series of tubes into a small nozzle, for atomization. The nebulizer of Ludwin “embodies a mask...adapted to fit over the nose and mouth” *Id.* page 1 left column, line 55 - page 1, right column line 2. Therefore, Ludwin discloses a nebulizer that uses heated, compressed air to pressurize a medicament, forcing the medicament through a nozzle into a mask to be worn over the mouth and nose.

In contrast, the instant invention related to a delivery system which urges active ingredients through the pores of the skin to reach the bones and mucous membranes below the skin. The air pressure applied via the pump inflates the elastic pad, pressing the compress against the wearer, and urging the active ingredients out of the compress and into the skin. However, unlike the pressurized air in Ludwin, the air in the instantly claimed mask never contacts the active ingredients. Further, the active ingredient present in the instant compress is soaked in water at 10°C (50°F), rather than heating as taught by Ludwin.

In contrast, Ludwin relates to a “medicament spraying apparatus” (Ludwin, page 2, right column, line 19) comprising, *inter alia*, a mask “adapted to fit over the nose and mouth” (*Id.* right column, lines 1-2), a nebulizer containing the medicament, a motor driven rotary compressor, and “suitable tubing connecting the compressor...to said nebulizer, and the nebulizer to said mask.” (*Id.* right column, lines 2-9).

The Examiner notes on page 7 of the Office Action, that the medicaments may be contained in a sponge member. However, upon review of the cited portion of Ludwin, specifically page 2, left column, lines 21-27, indicates an embodiment in which the sponge member is contained in a glass tube element of an injector. The injector is connected by a tube

to the compressor at a lower end, and the upper end fitted with injectors “which may be inserted in the nostrils.” From this description, one skilled in the art would understand that the sponge member is not a component of the mask, nor does the embodiment described allow unobstructed respiratory functions of the nostrils. Thus, Ludwin’s invention makes the nose and/or mouth of the wearer unavailable for normal respiratory function while introducing volatilized medicaments to the respiratory system of the wearer, in contrast to the unobstructed respiratory function of the nostrils and mouth instantly claimed. Additionally, Ludwin fails to teach or suggest the absorption of any medicament to bones underlying mucous membranes in the sinuses of a person in need thereof.

Marinello is directed to an apparatus applicable to the external orbital cavity for the treatment of internal wounds and inflammation of the ocular organs and central nervous system. *Marinello*, col. 3, lines 35-43. This reference fails to teach or suggest that the apparatus would be successful in providing medicament to any other tissue or structure. In fact, in column 3, lines 41-43, *Marinello* specifically recites that, “the apparatus can be used for the cure of internal injuries or inflammation of the eye and the central nervous system.” There is no suggestion that the apparatus is appropriate for the introduction of medicament into bone structures. Accordingly, *Marinello* fails to cure the deficiencies of Ludwin.

For at least the foregoing reasons, it is believed that revised independent claim 13 patentably distinguish over the relied upon portions of Ludwin and *Marinello*, either alone or in combination, and is therefore allowable. Independent claim 25 is similar or somewhat similar in scope to revised independent claim 13 and is therefore allowable for similar or somewhat similar

reasons to those for claim 13. Further, claims 14-24, which depend from claim 13, and claims 26-30 which depend from claim 25, are allowable as well.

Statements appearing above with respect to the disclosures in the cited references represent the present opinions of the Applicants' undersigned attorney and, in the event that the Examiner disagrees with any such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the respective reference providing the basis for a contrary view.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are patentable over the prior art, and an early and favorable consideration thereof is solicited.

Please charge any fees incurred by reason of this response and not paid herewith to
Deposit Account No. 50-0320.

Respectfully submitted,
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